

**REMARKS**

***Pending claims***

Claims 1, 5, 9-14, 17, 21, 25-28, 31, 33, 37, 41-46, 49, 53, 57-60, 63, 84 have been amended to more clearly point out and distinctly claim the invention. Support for the phrase "minimizing or eliminating biological concentration variability of said hormone in the tear fluid by wearing the contact lens on the eye for at least 30 minutes" can be found in the paragraph bridging page 5 and page 6; on page 15, the fifth paragraph; and the paragraph bridging page 15 and page 16. After this Amendment is entered, seventy two (72) Claims (claims 1-64 and 84-91) are pending.

***Drawings***

Applicants hereby submit two new drawings illustrating schematically tear-collecting devices according to preferred embodiments of the inventions. Applicants believe that no new matter has been introduced and that the objection of drawings has been overcome by the new drawings. Applicants respectfully request withdrawal of this objection.

***Specification amendments***

Applicants wish to thank the Examiner for the suggestion of a new title for this application. Applicants has amended the title as suggested by the examiner.

Applicants has amended the section of "BRIEF DESCRIPTION OF DRAWINGS" to include the newly added drawings, FIGs. 2A, 2B, and 3.

The third full paragraph on page 8 has been amended to update the information about the commonly-owned patent application which was incorporated by reference in its entirety.

The last paragraph on page 13 has been amended to update the information about the commonly-owned patent application (US2004/0076547 A1) which was incorporated by reference in its entirety.

The fourth paragraph on page 15 has been amended to include the description of newly added Figures 2A and 2B. The newly added test is copied from the incorporated reference (US2004/0076547, paragraph 0037).

The first full paragraph on page 16 has been amended to add the serial number of the cited reference.

The third full paragraph on page 23 has been amended to update the information about the co-pending patent application (US2003/0219909 A1) which was incorporated by reference in its entirety.

### **Rejections under 35 U.S.C. §102**

Claims 1, 9-17, 25-33, 41-49, 57-62, 84 and 86-91 were rejected under 35 U.S.C. 102(e) as being anticipated by Catt et al. (US 6,451,619). For the following reasons, the Examiner's rejection is respectfully traversed.

Applicants respectfully submit that the cited reference does not disclose nor teaches anything about collecting a tear fluid by the use of a tear-collecting device selected from the group consisting of a glass capillary, a hydrogel strip, and a contact lens. Catt et al. does not disclose anything about progesterone in a tear fluid, but instead discloses pregnenediol-3-glucuronide (P3G) in urine sample.

Moreover, to constitute an anticipatory reference, the prior art must contain an enabling disclosure. Chester v. Miller, 906 F.2d 1574, 1546 n.2 (Fed. Cir. 1990); see also Titanium Metals Corp. of Am. V. Banner, 778 F.2d 775, 781 (Fed. Cir. 1985); Scripps Clinic & Research Found. V. Genetech, Inc. 927 F.2d 1565, 1578 (Fed. Cir. 1991). The cited reference does not contain an enabling disclosure, more specifically it does not disclose nor appreciates that there exists a direct correlation between serum and tear concentrations of hormones of significance in relation to the fertility status of a female and/or to sex differentiation or dysfunction. Without knowing of such relationship and the possible existence of reproduction hormones in tear fluids, the mere mentioning of "tears" in the cited reference does not place the public in possession of the invention and cannot constitute legally cognizable prior art.

In sum, the cited reference does not anticipate the present invention as currently claimed, because the cited reference does not disclose all of the limitations of the invention as currently claimed and because it does not contain an enabling disclosure. Applicants respectfully request withdrawal of this rejection.

### **CLAIM REJECTIONS- 35 USC 103**

The Examiner has rejected claims 5-8, 21-24, 37-40 and 53-56 under 35 USC 103(a) as being obvious over Catt et al. (US 6,451,619) in view of Abreu (US 6,544,193). For the following reasons, the Examiner's rejection is respectfully traversed.

First, the primary reference cannot constitute a legally cognizable prior art because it does not contain an enabling disclosure for monitoring hormone concentration in a tear fluid as discussed above.

Second, even assuming *arguendo* that the primary reference would constitute a legally cognizable prior art, a *prima facie* case of obviousness has not been established, because the primary reference (Catt et al.), alone or in combination with the secondary references (Abreu), does not disclose or suggest all of the limitations of the invention as currently claimed. None of the primary reference and the secondary reference discloses or suggests, *inter alia*, anything about minimizing or eliminating of biological concentration variability of said hormone in the tear fluid by wearing the contact lens on the eye for at least 30 minutes, anything about a contact lens capable of binding said hormone, anything about a contact lens having surface charges present in a density sufficient to impart to the contact lens an increased adsorption of said hormone, anything about a contact lens having a coating comprising a receptor which binds specifically said hormone, anything about a contact lens having molecular imprints for said hormone, and anything about a contact lens having a core material that is prepared from a composition containing a receptor which binds specifically said hormone.

The examine alleged that Abreu teaches “using a contact lens having a core material (column 41, lines 61-63) that contains a receptor for specifically binding a hormone (column 17, lines 50-51).” However, the text cited by the examiner (column 17, lines 50-51) does not contain any words related to “receptor”. It is true that Abreu mentions hormones on col. 17, lines 48-53. But, Abreu is completely silent about a receptor which binds specifically said hormone. More importantly, a hormone is a substance ***totally different*** from a receptor which binds specifically said hormone. Applicants search the text of the secondary reference (Abreu) on the USPTO Website for the word “receptor” and obtain six matches as follows:

“...In this embodiment, the ICL uses blinking or closure of the eyes to activate remotely placed receptor photodiodes through the activation of an LED drive coupled with a pressure sensor.” (col. 21, lines 37-40) [Emphasis added]

“The quadriplegic patient focuses on a receptor photodiode and closes their eyes for 5 seconds, for example. The pressure exerted by the eyelid is sensed by the pressure sensor which is coupled with a timing chip. If the ICL is calibrated for 5 sec, after this amount of time elapses with eyes closed, the LED drive activates the LED which emits infrared light though the intervening eyelid tissue reaching suitable receptor photodiodes or suitable optical receivers connected to a power on or off circuit. ...” (col. 21, lines 41-45) [Emphasis added]

“FIG. 61 illustrates a contact device under an eyelid including a pressure sensor incorporated in a circuit having a power source, an LED drive and an LED for production of an LED signal for remote activation of a device having a photodiode or optical receiver on a receptor screen.” (col. 68, lines 35-39) [Emphasis added]

"By closure of the eye 1020 by the eye lids, the pressure sensor 1012 would be activated to energize the LED drive and therefore the LED for transmission of a signal 1020 to a remote photodiode or optical receiver 1022 located on a receptor system. ..." (col. 131, lines 23-27) [Emphasis added]

"... The use of the infrared wavelength including the use of LEDs results in delivering radiation that is minimally absorbed by photoreceptors in the retina. ..." (col. 174, lines 15-18) [Emphasis added]

Each time when Abreu mentions "receptors", Abreu associates this word specifically with photodiode or other optical elements. Nothing can be found in Abreu about a receptor which can specifically bind a hormone.

Moreover, the secondary reference does not contain an enabling disclosure for detection of ovulation by monitoring hormone concentration in a tear fluid. It is true that Abreu mentioned, in total four times, ovulation (Abstract, paragraph bridging col. 16 and col. 17, col. 22, lines 56-65, and paragraph bridging col. 22 and col. 23). But, considered as whole, Abreu teaches about detection of ovulation only by monitoring body temperature (col. 22, lines 56-65, and paragraph bridging col. 22 and col. 23). Abreu does not disclose anything about detection of ovulation by monitoring reproductive hormones in tear fluids. Abreu does not disclose nor appreciates that there exists a direct correlation between serum and tear concentrations of hormones of significance in relation to the fertility status of a female and/or to sex differentiation or dysfunction. Without knowing of such relationship, the mere mentioning of "ovulation" in the secondary reference does not place the public in possession of the invention and cannot constitute legally cognizable prior art.

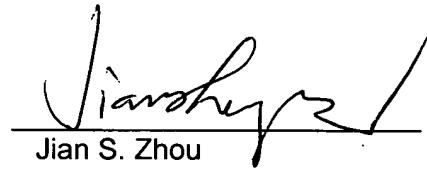
In sum, a *prima facie* case of obviousness has not been established. Applicant respectfully requests withdrawal of the 35 U.S.C. §103(a) rejection.

### CONCLUSION

In view of the foregoing and in conclusion, the Applicant submit that the rejections set-forth in the Office Action have been overcome, and that all pending claims are now in conditions for allowance.

Should the Examiner believe that a discussion with Applicants' representative would further the prosecution of this application, the Examiner is respectfully invited to contact the undersigned. The Commissioner is hereby authorized to charge any other fees which may be required under 37 C.F.R. §§1.16 and 1.17, or credit any overpayment, to Deposit Account No. 50-2965.

Respectfully submitted,

  
\_\_\_\_\_  
Jian S. Zhou  
Reg. No. 41,422  
(678) 415-4691

Date: Oct. 12, 2006

Novartis  
Corporate Intellectual Property  
One Health Plaza, Building 104  
East Hanover, NJ 07936-1080